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20.0 510(K) SMDA SUMMARY

510 (k) SUMMARY INFORMATION

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K013178

Prepared: September 10, 2001

Summiteer: Diagnostic Chemicals Limited

Address: West Royalty Industrial Park
16 McCarville Street
Charlottetown
P.E.I., C1A 2E6
Canada
(902) 566-1396

Contact: Nancy Olscamp

Device: Trade Name: DC-UIBC-CO_2-Calibrator
Common Name: DC-UIBC-CO_2-CAL

Classification: Division of Clinical Laboratory Devices
Panel- Clinical Chemistry
Classification Code- 75 JIS (Clinical Chemistry)

Predicate Devices: DC-UIBC-CAL, Cat. No. SE-090

Device Description:

DC-UIBC-CO_2 Calibrator is a human based, lyophilized serum which contains nonreactive stabilizers and additives.

Exercise the normal precautions required for handling all laboratory reagents. This product has been prepared exclusively from the blood of donors tested individually and shown by FDA-approved methods to be free from HBsAg and antibodies to HCV and HIV. However, as no test method can rule out the potential risk of infection with absolute certainty, the material should be treated just as carefully as a patient sample. In the event of exposure, the directives of the responsible Health Authorities should be followed.

Intended Use:

For in vitro diagnostic use as a calibrator in clinical chemistry assays for UIBC (Unsaturated Iron Binding Capacity) and CO_2 (Carbon Dioxide). DC-UIBC-CO_2 Calibrator may be used to check the linearity over the reportable patient range of UIBC assays.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 1 8 2001

Ms. Marlene J. Walker
Manager of Research and Development, Clinical Chemistry
Diagnostic Chemicals Limited
16 McCarville Street
Charlottetown, PE
Canada C1E 2A6

Re: k013178
Trade/Device Name: DC-UIBC-CO_2-Calibrator
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIX;
Dated: November 20, 2001
Received: November 21, 2001

Dear Ms. Walker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K013178

Device Name: **DC-UIBC-CO_2-Calibrator**

Indications for Use:

Clinical Chemistry assays may require a point of reference to determine the values of unknown samples. DC-UIBC-CO_2-CAL may be used for this purpose in UIBC and CO_2 assays.

For IN VITRO diagnostic use.

Thomas P. Noonan for Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K013178

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over the Counter Use** _____
(Per 21 CFR 801.109)